Ciclorox®

Ciclopirox USP

Description
Ciclorox® is a synthetic broad spectrum antifungal agent that inhibits the growth of pathogenic dermatophytes, yeasts, *Malassezia furfur, Trichophyton rubrum, Microsporum canis, Candida albicans* etc. In addition, **Ciclorox®** exerts antibacterial activity and anti-inflammatory activity.

Mode of action
The mechanism of action of **Ciclorox®** is poorly understood. **Ciclorox®** is thought to exert its antifungal activity by blocking fungal transmembrane transport, causing intracellular depletion of essential substrates (e.g. amino acids) and/or ions (e.g. potassium). **Ciclorox®** interferes with the synthesis of RNA and DNA.

Pharmacokinetics
Ciclorox® when applied as a topical is approximately 1.3% systemically absorbed. Protein binding is 94-97% after topical administration. Glucuronidation is the main metabolic pathway of **Ciclorox®** and biological half-life is 1.7 hours.

Composition
Ciclorox® 1% Cream: Each gram cream contains Ciclopirox Olamine USP 10 mg.
Ciclorox® 8% Topical Solution: Each gram contains Ciclopirox USP 80 mg.

Indications
Ciclorox® 1% Cream is indicated for the treatment of the following dermal infections:
- Tinea pedis
- Tinea cruris
- Tinea corporis due to *Trichophyton rubrum*
- *Trichophyton mentagrophytes*
- *Epidermophyton floccosum* and *Microsporum canis*
- Candidiasis (moniliasis) due to *Candida albicans*
- Tinea versicolor due to *Malassezia furfur* etc.

Ciclorox® 8% Topical Solution is indicated for the treatment of onychomycosis (fingernails & toenails) and immediately adjacent skin only.

Dosage & administration
Ciclorox® 1% Cream: Cream should be gently massaged onto the affected and surrounding skin areas twice daily for four weeks. Clinical improvement usually seen in the first week of treatment. If a patient shows no clinical improvement after four weeks of treatment the diagnosis should be re-determined. Patients with Tinea versicolor usually exhibit clinical and mycological clearing after two weeks of treatment.
Ciclorox® 8% Topical Solution: Before starting treatment, any loose nail or nail materials should be removed using nail files. Apply once daily (preferably at bed time) to the affected nails with the applicator brush provided. After applying medication, allow lacquer to dry approximately 30 seconds and wait 8 hours before taking a bath or shower. Once a week, remove the **Ciclorox®** 8% topical solution (nail lacquer) with alcohol pad. Using nail files, the damaged nail should be removed as much as possible.To prevent the solution from drying out, bottle should be closed tightly after every use.

Contraindications
Ciclorox® is contraindicated in individuals who have shown hypersensitivity to any of its components.

Side effects
Pruritus, burning sensation, headache, rash, irritation, dryness etc.

Adverse reactions
Ciclorox® is well tolerated with a low incidence of adverse reactions reported in clinical trials.

Use in pregnancy & lactation
USFDA Pregnancy category B.
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when **Ciclorox®** is administered to nursing women.

Precautions
For external use only.
Safety and effectiveness in children below the age of 12 years have not been established.

Warnings
Ciclorox® is not for ophthalmic use.

Drug interactions
There are no known drug interactions and none well documented.

Over dosage
An overdose of **Ciclorox®** is not expected to be dangerous topically.
Do not use extra medicine to make up the missed dose topically.

Storage
Store in a cool (Below 30˚C temperature) and dry place protected from light. Keep out of the reach of children.

Packaging
Ciclorox® 1% Cream: Each pack has lami tube containing 15 gm cream.
Ciclorox® 8% Topical Solution: Each pack has glass bottle fitted with brush containing 6 ml solution.

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Opsonin Pharma
Ideas for healthcare

Manufactured by
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